

1 DAVID C. ANDERSEN (State Bar No. 194095)
2 THE MILLER FIRM, LLC
3 108 Railroad Avenue
4 Orange, VA 22960
5 Telephone: (540) 672-4224
6 Facsimile: (540) 672-3055
7 Email: dandersen@doctoratlaw.com

8
9 **UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA**
10 **SAN FRANCISCO DIVISION**
11

12 Case No. 3:07-cv-05887-JL

13
14 JAMES HALL

15
16 Plaintiff,

17
18
19
20
21
22 v.

23
24
25 SMITHKLINE BEECHAM
26 CORPORATION
27 d/b/a GLAXOSMITHKLINE and
28 MCKESSON CORPORATION

29
30 Defendants

PLAINTIFF'S NOTICE
OF MOTION
AND MOTION
FOR REMAND WITH
SUPPORTING
MEMORANDUM;
[PROPOSED] ORDER

HEARING:
DATE: December 6, 2007
TIME: 10:00 A.M.
COURTROOM: B
JUDGE: Magistrate Judge Maria-Elena James

TABLE OF CONTENTS

| | | |
|----|--|------------|
| 1 | | |
| 2 | | |
| 3 | TABLE OF CONTENTS | ii |
| 4 | TABLE OF AUTHORITIES | iii |
| 5 | TABLE OF EXHIBITS | v |
| 6 | NOTICE | 1 |
| 7 | I. INTRODUCTION | 2 |
| 8 | II. FACTUAL BACKGROUND | 3 |
| 9 | III. STANDARD OF REVIEW | 4 |
| 10 | IV. LACK OF SUBJECT MATTER JURISDICTION | 5 |
| 11 | V. PLAINTIFF HAS ALLEGED A VALID CAUSE | 7 |
| 12 | OF ACTION AGAINST MCKESSON | |
| 13 | | |
| 14 | VI. DEFENSE OF LEARNED INTERMEDIARY | 9 |
| 15 | IS INAPPROPRIATE | |
| 16 | | |
| 17 | VII. FEDERAL QUESTION JURISDICTION | 9 |
| 18 | | |
| 19 | VIII. THE PRESCRIPTION DRUG USER FEE | 11 |
| 20 | REAUTHORIZATION ACT ABOLISHES | |
| 21 | DEFENDANT’S ALLEGED | |
| 22 | PREEMPTION DEFENSE | |
| 23 | | |
| 24 | IX. CONCLUSION | 12 |
| 25 | | |
| 26 | [PROPOSED] ORDER | 14 |

TABLE OF AUTHORITIES

I. CASES

A. UNITED STATES SUPREME COURT

| | |
|---|----|
| <i>Gully v. First National Bank</i> , 299 U.S. 109, 113 (1936)..... | 9 |
| <i>Caterpillar, Inc. v Williams</i> , 482 U.S. 386, 392 (1987)..... | 9 |
| <i>Beneficial National Bank v. Anderson</i> , 539 U.S. 1, 6-8 (2003)..... | 9 |
| <i>Grable & Sons Metal Prods. V. Darue Eng'g & Mfg.</i> , 545 U.S. 312 (U.S. 2005)..... | 9 |
| <i>Franchise Tax Board v. Constr. Laborers Vacation Trust for S. Calif.</i> , 463 U.S.1 (U.S. 1983)..... | 10 |
| <i>Merrell Dow Pharm., Inc., v. Thompson</i> , 478 U.S. 804 (1986)..... | 10 |

B. CALIFORNIA COURTS

| | |
|---|---|
| <i>Perkins v. Superior Court</i> , 117 Cal.App.3d 1, 6 (2 nd Dist. 1981)..... | 7 |
| <i>C.f., Barth v. B.F. Goodrich Tire Co.</i> , 265 Cal. App.2d.228 (1 st Dist. 1968)..... | 8 |

C. SECOND CIRCUIT COURT OF APPEALS

| | |
|---|---|
| <i>Sullivan v. American Airlines, Inc.</i> , 424 F.3d 267, 276 (2d Cir. 2005)..... | 9 |
|---|---|

D. THIRD CIRCUIT COURT OF APPEALS

| | |
|--|---|
| <i>Boyer v. Snap-On Tools Corp.</i> , 913 F.2d 108 (3 rd Cir. 1990)..... | 6 |
|--|---|

E. FIFTH CIRCUIT COURT OF APPEALS

| | |
|---|---|
| <i>Dodson v. Spiliada Maritime Corp.</i> , 951 F.2d 40, 42-43 (5 th Cir. 1992)..... | 4 |
|---|---|

| | | |
|----|---|----|
| 1 | <i>Green v. Amerada Hess Corp.</i> , | |
| 2 | 707 F.2d 201, 204 (5 th Cir. 1983)..... | 6 |
| 3 | <i>Jernigan v. Ashland Oil Co.</i> , | |
| 4 | 989 F.2d 812, 815-816 (5 th Cir. 1993)..... | 6 |
| 5 | | |
| 6 | <i>Ford v. Elsbury</i> , | |
| 7 | 32 F.3d 931, 938 (5 th Cir. 1994)..... | 6 |
| 8 | | |
| 9 | <i>Green v. Amerada Hess Corp.</i> , | |
| 10 | 707 F.2d 201, 205 (5 th Cir. 1983)..... | 6 |
| 11 | | |
| 12 | | |
| 13 | <u>F. NINTH CIRCUIT COURT OF APPEALS</u> | |
| 14 | <i>Morris v. Princess Cruises, Inc.</i> , | |
| 15 | 236 F.3d 1061, 1067 (9 th Cir. 2001)..... | 4 |
| 16 | <i>McCabe v. General Foods Corp.</i> , | |
| 17 | 811 F.2d 1336, 1339 (9 th Cir. 1987)..... | 4 |
| 18 | <i>Peloza v. Capistrano Unified Sch. Dist.</i> , | |
| 19 | 37 F.3d 517, 521 (9 th Cir. 1994)..... | 4 |
| 20 | <u>G. UNITED STATES DISTRICT COURTS FOR NORTHERN, CENTRAL,</u> | |
| 21 | <u>EASTERN, AND SOUTHERN DISTRICTS OF CALIFORNIA</u> | |
| 22 | | |
| 23 | <i>Plute v. Roadway Package Sys., Inc.</i> , | |
| 24 | 141 F. Supp. 2d 1005, 1008 (N.D. Cal. 2001)..... | 4 |
| 25 | | |
| 26 | <i>Brown v. Allstate, Ins. Co.</i> , | |
| 27 | 17 F.Supp.2d 1134 (D. Cal. 1998)..... | 7 |
| 28 | | |
| 29 | | |
| 30 | <u>H. UNITED STATES DISTRICT COURTS FOR</u> | |
| 31 | <u>NON-CALIFORNIA DISTRICTS</u> | |
| 32 | | |
| 33 | | |
| 34 | <i>Little v. Purdue Pharma, LP</i> , | |
| 35 | 227 F. Supp. 2d 838, 847 n. 12 (S.D. Ohio 2002)..... | 5 |
| 36 | | |
| 37 | <i>Freeman v. Bragunier Masonry Contractors, Inc.</i> , | |
| 38 | 928 F. Supp. 611 (Dist. Md. 1996)..... | 6 |
| 39 | | |
| 40 | <i>State of Utah v. Eli Lilly & Co.</i> , | |
| 41 | 2007 U.S. Dist. Lexis 65571 (D. Utah 2007)..... | 10 |

| | | |
|---|---|----|
| 1 | | |
| 2 | <i>Commonwealth of Pennsylvania v. Eli Lilly & Co., Inc.,</i> | |
| 3 | 2007 U.S. Dist. Lexis 46946 (E.D. Pa. 2007)..... | 10 |
| 4 | | |

I. CALIFORNIA SUPREME COURT

| | | |
|---|--|---|
| 5 | | |
| 6 | | |
| 7 | | |
| 8 | <i>Anderson v. Owens-Corning Fiberglas Corp.,</i> | |
| 9 | 53 Cal.3d 987, 281 Cal. Rptr. 528, 810P.2d 549 (1991)..... | 7 |

| | | |
|----|--|---|
| 10 | | |
| 11 | <i>Jimenez v. Superior Court,</i> | |
| 12 | 29 Cal.4 th 473 (2002)..... | 7 |
| 13 | | |

II. OTHER AUTHORITIES

| | | |
|----|-----------------------|------|
| 14 | | |
| 15 | | |
| 16 | | |
| 17 | | |
| 18 | 28 U.S.C. § 1332..... | 4, 5 |

| | | |
|----|--------------------------|---|
| 19 | 28 U.S.C. § 1441(b)..... | 4 |
|----|--------------------------|---|

| | | |
|----|--------------------------|---|
| 20 | 28 U.S.C. § 1447(c)..... | 5 |
|----|--------------------------|---|

| | | |
|----|---|---|
| 21 | Cal. Bus. & Prof. Code § 17200, et seq..... | 6 |
|----|---|---|

| | | |
|----|---|---|
| 22 | Consumer Legal Remedies Act, Civ. Code § 1750 et seq. (“CLRA”)..... | 6 |
|----|---|---|

| | | |
|----|--|---|
| 23 | California Code of Civil Procedure § 425.10(b)(1)..... | 7 |
|----|--|---|

| | | |
|----|--------------------------|---|
| 24 | 28 U.S.C. § 1441(a)..... | 9 |
|----|--------------------------|---|

| | | |
|----|---|---|
| 25 | <i>Order Denying Plaintiff’s Motion to Remand,</i> | |
| 26 | <i>In re: Phenylpropanolamine(PPA) Products Liability Litigation,</i> | |
| 27 | MDL No. 1407, Docket No. C02-423R, | |
| 28 | Slip Op. (W.D. Wash. Nov. 27, 2002)..... | 8 |

| | | |
|----|--|--------|
| 29 | | |
| 30 | 71 Fed. Reg. 3922 (Jan. 24, 2006)..... | 11, 12 |

| | | |
|----|--|--------|
| 31 | | |
| 32 | Prescription Drug User Free Reauthorization Act (PDUFA), | |
| 33 | H.R. 3580H.R. 3580 (Sept. 27, 2007)..... | 11, 12 |
| 34 | | |

TABLE OF EXHIBITS

- A. Notice of Ruling with attached Revised Ruling on Request for Reconsideration by Judge Victoria Chaney), *Vioxx Cases*, California Superior Court for Los Angeles County, Case No. JCCP 4347, filed on or about May 22, 2006.
- B. *Reid, et al., v. Merck & Company, Inc., et al.*, Case No. CV 02-00504 NM (RZx)
- C. *Black, et al., v. Merck & Company, Inc., et al.*, Case No. CV 03-8730 NM (AJWx)
- D. *Albright, et al. v. Merck & Co., Inc., et al.*, No CV 05-4025 JFW (MANx)
- E. *Aaroe, et al., v. Merck & Co., Inc., et al.*, No CV05-5559 JFW (CWx)
- F. *Maher v. Novartis Pharmaceuticals Corp., et al.*, No. 07-852 WQH (JMA)
- G. Declaration of David C. Andersen Regarding Exhibits A-F.

NOTICE

PLEASE TAKE NOTICE that on December 6, 2007, at 10:00 A.M., or as soon thereafter as the matter may be heard in Courtroom B of the above entitled Court, located at 450 Golden Gate Avenue, San Francisco, CA 94102, Plaintiff will move the Court to remand this action to the SUPERIOR COURT OF THE STATE OF CALIFORNIA FOR AND IN THE COUNTY OF SAN FRANCISCO, NORTHERN DISTRICT. This remand is proper as no diversity exists among the parties as required by 28 U.S.C. § 1132 and there is no substantial federal question requiring federal jurisdiction.

This motion will be based on this Notice of Motion and Motion, the Memorandum of Points and Authorities filed herewith, and the pleadings and papers filed herein.

Dated: December 3, 2007

/s/

David C. Andersen (Bar No. 194095)
THE MILLER FIRM, LLC
Attorneys for Plaintiff
108 Railroad Avenue
Orange, VA 22960
Phone: (540) 672-4224
Fax: (540) 672-3055
Email: dandersen@doctoratlaw.com

PLAINTIFFS' MOTION FOR REMAND AND
SUPPORTING MEMORANDUM

Plaintiffs, by attorneys, THE MILLER FIRM, LLC, file this Motion for Remand against Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") and McKesson Corporation ("McKesson") (collectively "Defendants"), and state as follows:

I.
INTRODUCTION

Plaintiffs filed a complaint in the Superior Court of California against GSK and McKesson, for injuries and damages suffered when Plaintiff used Avandia® (hereinafter, Avandia"), as manufactured and distributed by all of the Defendants. McKesson is a "citizen" of the State of California for diversity purposes and may, from time to time, be referred to as "Non-Diverse Defendant". GSK may be referred to as "Diverse Defendant".

On November 20, 2007, GSK removed this action alleging that McKesson, the only in-state Defendant, has been fraudulently joined. GSK's claims that McKesson can not be liable and that it is a fraudulent defendant were raised and rejected in Vioxx cases filed in the California Superior Court for Los Angeles County, JCCP Case No. 4247. (Notice of Ruling with attached Revised Ruling on Request for Reconsideration by Judge Victoria Chaney), *Vioxx Cases*, California Superior Court for Los Angeles County, Case No. JCCP 4347, filed on or about May 22, 2006, Andersen Declaration at **Exhibit A**).

Other California courts have granted remand based upon the same arguments herein raised. (See rulings in *Reid, et al., v. Merck & Company, Inc., et al.*, Case No. CV 02-00504 NM (RZx) (Andersen Declaration at **Exhibit B**); *Black, et al., v. Merck & Company, Inc., et al.*, Case No. CV 03-8730 NM (AJWx) (Andersen Declaration at **Exhibit C**); *Albright, et al. v. Merck & Co., Inc., et al.*, No CV 05-4025 JFW (MANx) (Andersen Declaration at **Exhibit D**); and *Aaroe, et al., v. Merck*

1 & Co., Inc., et al., No CV05-5559 JFW (CWx) (Andersen Declaration at **Exhibit E**); *Maier v.*
2 *Novartis Pharmaceuticals Corp., et al.*, No. 07-852 WQH (JMA) (Andersen Declaration at **Exhibit**
3 **F**).

4 GSK argues: (1) that Plaintiffs failed to state a cause of action against the resident
5 defendant; (2) that Plaintiff's claims necessarily raise substantial federal questions; (3) that under
6 preemption principles, FDA approval of labeling under the act preempts conflicting or contrary
7 State law. As will be set forth below, GSK is wrong on these counts, and this case should be
8 remanded to state court.

9 First, contrary to GSK's representation, Plaintiffs pleaded facts sufficient to state the
10 multiple causes of action against McKesson which will be outlined below. Further, GSK asks this
11 Court to ignore the numerous times McKesson is identified by name within Plaintiff's Complaint,
12 and the factual detail of McKesson's activities by name. Plaintiffs have pleaded facts to satisfy all
13 of the elements to state a products liability claim under California law. Accordingly, GSK's first
14 basis for remand must be rejected.

15 Second, GSK cannot demonstrate that Plaintiffs have raised a substantial federal question
16 that would require federal jurisdiction. As explained below, Plaintiffs' claims do not raise a
17 "substantial federal question" because application of federal law is not necessary for their
18 resolution. Conversely, Plaintiffs claims rest in State causes of action in which the State of
19 California has a significant judicial interest, requiring these claims to be tried in State Court.

20 Third, with the adoption of the Prescription Drug User Fee Reauthorization Act (PDUFA),
21 signed into law September 27, 2007, any argument by Defendant that FDA approval of product
22 labeling preempts state law claims is without merit.

23 **II.**
24 **FACTUAL BACKGROUND**

- 1 1. On October 11, 2007, Plaintiffs filed an action in the Superior Court of the State of
- 2 California for the County of San Francisco.
- 3 2. Defendants filed their answer to Plaintiffs Complaint on November 19, 2007.
- 4 3. On November 20, 2007, Defendants filed their Notice of Removal.

5 III.

6 STANDARD OF REVIEW

7 The burden to support removal is always upon the party seeking it. Here, that is not

8 Plaintiff. Should GSK supply an opposition to remand, Plaintiffs reserve the right to address

9 anything new and do not waive the right to attach any appropriate documentation to support their

10 position.

11 For removal based on diversity, 28 U.S.C. § 1332 requires complete diversity of citizenship.

12 *Morris v. Princess Cruises, Inc.*, 236 F.3d 1061, 1067 (9th Cir. 2001). Additionally, removal is not

13 allowed where one of the defendants is a “citizen of the State in which such action is brought.” *See*

14 28 U.S.C. § 1441(b). McKesson is a “citizen” of California. If McKesson can be a party, removal

15 is improper. Joinder of a resident defendant is only fraudulent if the plaintiff fails to state a cause of

16 action against that defendant and the failure is obvious according to the settled rules of the state.

17 *McCabe v. General Foods Corp.*, 811 F.2d 1336, 1339 (9th Cir. 1987).

18 “There is a presumption against finding fraudulent joinder, and defendants who assert that

19 [the] plaintiff has fraudulently joined a party carry a heavy burden of persuasion.” *Plute v.*

20 *Roadway Package Sys., Inc.*, 141 F. Supp. 2d 1005, 1008 (N.D. Cal. 2001). Courts have denied

21 claims of fraudulent joinder when there is any possibility that a plaintiff may prevail on the cause of

22 action against the in-state defendant. *Plute*, 141 F.Supp.2d at 1008, 1012. “In determining whether

23 a defendant was joined fraudulently, the court must resolve ‘all disputed questions of fact and all

24

ambiguities in the controlling state law in favor of the non-removing party.’” *Plute*, 141 F. Supp. 2d at 1008 (quoting *Dodson v. Spiliada Maritime Corp.*, 951 F.2d 40, 42-43 (5th Cir. 1992)).

Furthermore, any doubts concerning the sufficiency of a cause of action due to inartful, ambiguous or technically defective pleading must be resolved in favor of remand; a lack of clear precedent does not render the joinder fraudulent. *Plute*, 141 F.Supp 2d at 1008; *See Pelozo v. Capistrano Unified Sch. Dist.*, 37 F.3d 517, 521 (9th Cir. 1994) (courts must interpret general allegations to “embrace whatever specific facts might be necessary to support them”); *Little v. Purdue Pharma, LP*, 227 F. Supp. 2d 838, 847, n. 12 (S.D. Ohio 2002) (“in light of the heavy burden on defendants to show the non-diverse defendants were fraudulently joined, it seems to this Court that a finding of fraudulent joinder should not be based on factual deficiencies within the pleadings which are correctable by amendment”).

Here, Defendants must show by clear and convincing evidence that under no circumstances could McKesson be liable for any of Plaintiffs’ claimed injuries.

IV. **LACK OF SUBJECT MATTER JURISDICTION**

Federal diversity jurisdiction requires that all parties to the action be “citizens of different states” or “citizens or subjects of a foreign state.” 28 U.S.C. § 1332. 28 U.S.C. § 1447(c) governs the procedure after removal, and allows for remand of any action where the district court lacks subject matter jurisdiction. Specifically, 28 U.S.C. § 1447(c) states in pertinent part: “If any time before final judgment it appears that the district court lacks subject matter jurisdiction, the case shall be remanded.” Defendant’s removal is improper because the district court lacks subject matter jurisdiction as the local corporation has been properly joined.

Defendants removed this action based solely upon diversity jurisdiction. They imply that the parties to this action are completely diverse because the local defendant, McKesson, is a

1 fraudulently joined defendant. To succeed, Defendant must point to some California law that
2 clearly indicates joinder is fraudulent. Plaintiff has sued McKesson under (1) negligence; (2)
3 negligent failure to warn; (3) negligence per se; (4) negligent misrepresentation; (5) breach of
4 express warranty; (6) breach of implied warranty; (7) strict products liability – defective design; (8)
5 strict products liability – manufacturing and design defect; (9) strict products liability – failure to
6 adequately warn; (10) fraudulent misrepresentation; and (11) violations of California Unfair Trade
7 Practices and Consumer Protection Law which are recognized causes of action against distributors
8 and designers of medications in the State of California. *See* Cal. Bus. & Prof. Code § 17200, et
9 seq. and the Consumer Legal Remedies Act, Civ. Code § 1750 et seq. (“CLRA”).

10 Defendants seek a ruling that would in effect decide substantial factual disputes and
11 terminate Plaintiffs causes of action against McKesson. The effect of allowing removal would be to
12 find there is no way McKesson could ever have any liability here. However, a district court must
13 not decide substantive factual issues in order to answer the threshold question of whether joinder of
14 an in-state defendant is fraudulent. *Green v. Amerada Hess Corp.*, 707 F.2d 201, 204 (5th Cir.
15 1983). The only issue the court should address is its own jurisdiction. *Id.*, at 204.

16 The removing defendant has the heavy burden of alleging and proving the non-diverse
17 party’s joinder is “fraudulent.” *Jernigan v. Ashland Oil Co.*, 989 F.2d 812, 815-816 (5th Cir. 1993);
18 *Boyer v. Snap-On Tools Corp.*, 913 F.2d 108 (3rd Cir. 1990). In order to establish that plaintiffs
19 fraudulently joined an in-state defendant for purposes of defeating removal jurisdiction, the
20 defendant must show either (1) that there is no possibility that the plaintiff would be able to
21 establish a cause of action against the in-state defendant in state court, or (2) that there has been
22 outright fraud in plaintiff’s pleading of jurisdictional facts. *Freeman v. Bragunier Masonry*

1 *Contractors, Inc.*, 928 F. Supp. 611 (Dist. Md. 1996); *Ford v. Elsbury*, 32 F.3d 931, 938 (5th Cir.
2 1994); *Green v. Amerada Hess Corp.*, 707 F.2d 201, 205 (5th Cir. 1983).

3 As is more fully set out below, the allegations of the Complaint state causes of action
4 against McKesson. In addition, the Southern and Central Districts of California have all held, in
5 cases involving substantially similar allegations, that McKesson is not fraudulently joined in cases
6 involving the pharmaceutical drugs. See, e.g. *Black, Albright, Aaroe, and Maher* attached as
7 Exhibits “C”, “D”, “E” and “F”. These cases, coupled with substantive law, support that McKesson
8 is not fraudulently joined.

9 **V.**
10 **PLAINTIFF HAS ALLEGED A VALID CAUSE OF ACTION AGAINST MCKESSON**

11
12 Plaintiff has alleged all causes of action against McKesson. Defendants assert that
13 McKesson is fraudulently joined because “plaintiffs have failed to make any material allegations
14 against it”. See Defendant’s Notice of Removal ¶ 20. In support of this argument Defendants rely
15 on *Brown v. Allstate Insurance*, a case in which the Court found fraudulent joinder because the
16 defendants were not individually named in the body of the complaint and there were no allegations
17 made of wrongdoing by any of the defendants. *Brown v. Allstate Insur.*, 17 F. Supp. 2d 1134, 1137.
18 Here, however, McKesson is both named throughout the body of the complaint and allegations of
19 wrongdoing are made against it.

20 Without these concerns, under California law, Plaintiffs’ Complaint must only contain, “a
21 statement of the facts constituting the cause of action in ordinary and concise language.” California
22 Code of Civil Procedure § 425.10(b)(1). This has been interpreted to mean that Plaintiffs are
23 required only to plead “sufficient facts to apprise the Defendant(s) of the basis upon which the
24 Plaintiff(s) [are] seeking relief.” *Perkins v. Superior Court*, 117 Cal.App. 3d 1, 6 (2nd Dist. 1981).

1 Defendants' argument that McKesson is fraudulently joined is directly contrary to well
2 established strict liability law in California. A distributor, unlike pharmacists, is liable for failure to
3 warn. *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal.3rd 987, 281 Cal. Rptr. 528, 810 P.2d
4 549 (1991); see *Jimenez v. Superior Court*, 29 Cal. 4th 473 (2002). Therefore, specific and valid
5 allegations of failure to warn can be made against each GSK and McKesson.

6 Second, it is not inconsistent to argue that *both* GSK and McKesson were aware, or should
7 have been aware, of the scientifically knowable risks of Avandia. McKesson is neither a pharmacy
8 retailer nor a physician, which are specified as parties not able to be sued for failure to warn. *See*
9 *Order Denying Plaintiff's Motion to Remand, In re: Phenylpropanolamine (PPA) Products*
10 *Liability Litigation*, MDL No. 1407, Docket No. C02-423R, Slip Op. (W.D. Wash. Nov. 27, 2002).
11 McKesson is, among other things, a sophisticated pharmaceutical distributor, in the direct chain of
12 distribution of Avandia, that knew or should have known of the dangers of Avandia and warned
13 Plaintiff of those dangers. Defendant's reliance on any case precluding claims against doctors and
14 drug stores would be misplaced.

15 It is alleged that McKesson, by and through its agents, worked with the Diverse Defendant
16 to develop and distribute Avandia without appraising Plaintiff and/or her treating physicians of
17 known or knowable dangers and without adequately warning of those known or knowable dangers.
18 McKesson had a program in place to assist in product promotion. This is not a company that was
19 merely a conduit for the drug. It was actively engaged in promotion and cannot hide behind the
20 cloak of innocence which could attach under any strict interpretation of the lack of fault that could
21 be attached to a distributor which is merely a clearinghouse. *C.f., Barth v. B.F. Goodrich Tire Co.*,
22 265 Cal. App. 2d.228 (1st Dist. 1968).

1 *Williams*, 482 U.S. 386, 392 (1987). The plaintiff's statement of the cause of action must
2 affirmatively show it is based on federal law. *Beneficial National Bank v. Anderson*, 539 U.S. 1 at
3 6-8.

4 A rare form of "arising under" jurisdiction is created if the complaint, under scrutiny,
5 contains state law based theories of recovery that implicate significant federal issues. *Grable &*
6 *Sons Metal Prods. v. Darue Eng'g & Mfg.*, 545 U.S. 312 (U.S. 2005). This form of "arising under"
7 jurisdiction has been stated as a two part test. First, it must appear from the complaint that "the
8 right to relief depends upon the construction or application of federal law" and involves a contested
9 federal issue. *Id.* at 313. Further, the underlying federal issue must be sufficiently "substantial"
10 such that there is a clear indication of a "serious federal interest in claiming the advantages thought
11 to be inherent in a federal forum." *Id.* at 313.

12 Mere existence of a federal issue is insufficient to confer jurisdiction. Rather, the second
13 prong requires that the "federal jurisdiction is consistent with congressional judgment about the
14 sound division of labor between state and federal courts governing the application of § 1331." *Id.*
15 Should the purported federal question fail under either of the inquiries, there is no federal
16 jurisdiction.

17 Because Plaintiffs rely on multiple causes of action against distributors and designers of
18 medications recognized in the State of California, including violations of California Unfair Trade
19 Practices and Consumer Protection Law, application of the well pleaded complaint rule requires that
20 they be permitted to pursue their claims in state court.

21 Defendants' removal is improper as Plaintiffs' State claims do not involve a substantial
22 contested federal issue. In order for a federal question to be significant or substantial, the federal
23 issue "must be actually disputed, and essential to the adjudication of the plaintiff's claim." *State of*

1 *Utah v. Eli Lilly & Co.*, 2007 U.S. Dist. Lexis 65571 (D. Utah 2007); quoting *Commonwealth of*
 2 *Pennsylvania v. Eli Lilly & Co. Inc.*, 2007 U.S. Dist. Lexis 46946 (E.D. Pa. 2007) (citing *Grable*,
 3 545 U.S. at 313). Under the substantial federal question doctrine, a state law cause of action
 4 actually arises under federal law, even though Congress has not provided a federal private right of
 5 action, “where the vindication of a right under state law necessarily turn[s] on some construction of
 6 federal law.” *Franchise Tax Board v. Constr. Laborers Vacation Trust for S. Calif.*, 463 U.S. 1, 9
 7 (1983).

8 However, the incorporation of a federal standard in a state law action does not implicate the
 9 substantial federal question doctrine. *Merrell Dow Pharm., Inc. v. Thompson*, 478 U.S. 804 (1986).
 10 As in the current case, *Merrell Dow* involved allegations both that inadequate warnings on a drug’s
 11 label and promotion of that drug were in violation of the Federal Food, Drug & Cosmetic Act. *Id.*
 12 at 806. The FDCA does not create a private right of action for violation of the misbranding
 13 provision. The Court found that the mere presence of a federal standard embedded in a state law
 14 cause of action is not enough to warrant federal question jurisdiction. *Id.* at 810-12. The Court
 15 noted the “significance of the necessary assumption that there is no federal private cause of
 16 action...cannot be overstated. *Id.* at 812. Further, the Court concluded that “the congressional
 17 determination that there should be no federal remedy for the violation of this federal statute is
 18 tantamount to a congressional conclusion that the presence of a claimed violation of the statute as
 19 an element of a state cause of action is insufficiently ‘substantial’ to confer federal question
 20 jurisdiction.” *Id.* at 814.

21 **VIII.**
 22 **THE PRESCRIPTION DRUG USER FEE REAUTHORIZATION ACT ABOLISHES**
 23 **DEFENDANT’S ALLEGED PREEMPTION DEFENSE**
 24

1 Defendant cites 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006), claiming that under this rule FDA
 2 approval of labeling under the act preempts conflicting or contrary State law. However, this claim
 3 is without merit. On September 27, 2007, the Prescription Drug User Free Reauthorization Act
 4 (PDUFA) H.R. 3580 was signed into law.¹ Congress, for the first time through legislation, placed
 5 the burden of updating the warning label of a prescription drug squarely on the drug company. *See*
 6 PDUFA, H.R. 3580. The law expressly stipulates that the manufacturer has the responsibility to
 7 promptly update its drug label when the manufacturer becomes aware of safety information that
 8 should be added to the label. Thus, even if the FDA does not act in requiring a label change, the
 9 drug company still has the burden to update its warning label.

10 The attempt by the FDA in the Preamble to its recent rules to create a purported preemptive
 11 effect of FDA approved labels, 71 Fed. Reg. 3922 (Jan 24, 2006), is now clearly superseded by
 12 federal law. With the adoption of PDUFA, any argument by Defendant that FDA approval of
 13 product labeling preempts state law claims related to the adequacy of prescription drug warnings is
 14 undoubtedly moot. The burden of updating the label with respect to the serious side effects of
 15 Avandia rests squarely with the Defendant.

16 **IX.** 17 **CONCLUSION** 18

19 Defendant has failed to meet its heavy burden to remove this state law action. For all the
 20 foregoing reasons, Plaintiff respectfully requests that this action be remanded to the Superior Court
 21 of California, County of San Francisco.
 22
 23
 24

¹ PDUFA became effective on October 1, 2007.

1
2
3 Dated: December 3, 2007

Respectfully submitted,

4
5
6 /s/

7 David C. Andersen (Bar No. 194095)

8 THE MILLER FIRM, LLC

9 Attorneys for Plaintiff

10 108 Railroad Avenue

11 Orange, VA 22960

12 Phone: (540) 672-4224

13 Fax: (540) 672-3055

14 Email: dandersen@doctoratlaw.com

[PROPOSED] ORDER

Having read and considered all arguments made in the above matter, and having decided that based on all moving papers and arguments that no diversity and no federal question exists in this case, it is hereby remanded to the Superior Court of San Francisco.

Dated

Hon. Maria-Elena James

CERTIFICATE OF SERVICE

I hereby certify that on December 3, 2007, a true and correct copy of the foregoing were delivered via facsimile to:

Donald. F. Zimmer
Krista Cosner
Drinker Biddle & Reath LLP
50 Fremont Street, 20th Floor
San Francisco, CA 94105

Dated: December 3, 2007

Respectfully submitted,

_____/s/_____
David C. Andersen (Bar No. 194095)
THE MILLER FIRM, LLC
Attorneys for Plaintiff
108 Railroad Avenue
Orange, VA 22960
Phone: (540) 672-4224
Fax: (540) 672-3055
Email: dandersen@doctoratlaw.com